



Session on Genomic Data Sharing:

Empowered ~~Consumer Controlled~~ Genomic Data Sharing Model

21st Meeting of the SACGHS
Washington, D.C. ♦ February 4, 2010

Robert H. Shelton
Private Access, Inc.
Chairman & CEO



About Private Access / Why I am here

Parent

Son prenatally diagnosed with genetic condition

Advocate

Chaired national disease advocacy group for 6 years

Focused Private Access to address a need we recognized

Entrepreneur

Founded private technology company

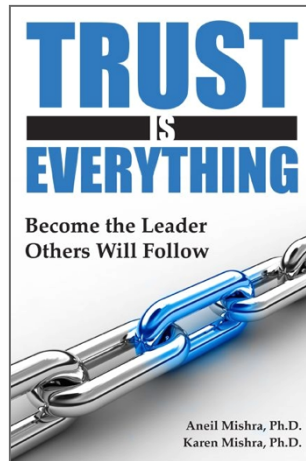
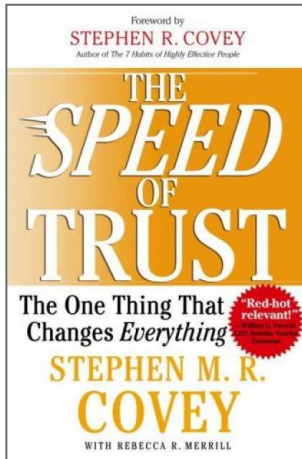
Not just an idea, but today hundreds of thousands of lines of software code enabling a data privacy / accessibility platform

Partner

We believe our privacy technology can, among other things, increase the pace of clinical trials and the strength advocacy



Our Mission: Creating an Environment of Trust™



PRIVACY IS
a huge speed bump in the race
toward healthcare data liquidity

PRIVACY IS
an achievable goal that will help
enable the promise of HIE

*“The new economy begins with
technology and ends with trust.”*

Alan Webber
Founder, Fast Company



Using Technology to Strike the Perfect Balance

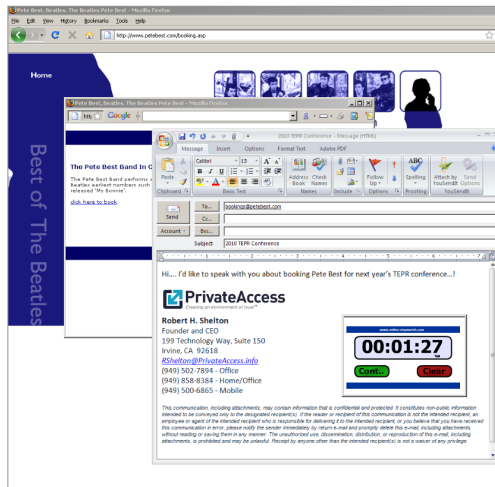


To be the market and thought leader for privacy and access to confidential information, empowering people to safely leverage the Internet to improve their lives



Speed and Ease of Internet Search Technology

Locate a Public Figure
and Data About Them



< 1.5 Minutes

Locate a Date (or Employee)
and Data About Them



< 3 Minutes

Why Not in Health Care?



Days, weeks or months





Why is Empowering Consumers So Important?

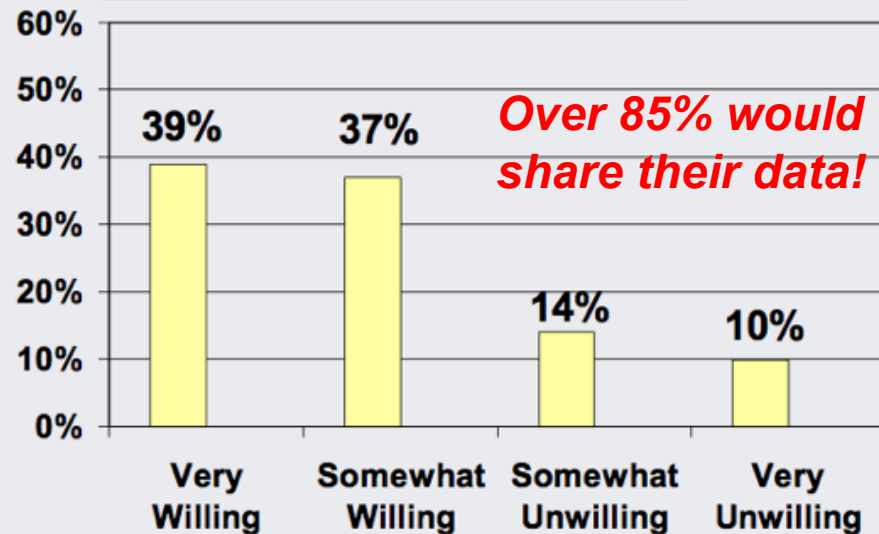
"How willing are you to have your child's blood sample (from newborn screening) used for future research studies, with (or without) your permission?"

Four choices were:

- *Very willing*
- *Somewhat willing*
- *Somewhat unwilling*
- *Very unwilling*

Use of NBS Sample for Research

With Parental Permission



Source: Dr. Aaron Goldenberg (Case Western Reserve), *Public Health Genomics*, July 9, 2009 (as reported at Genetic Alliance Conference on Newborn Screening, December 2009).

CASE WESTERN RESERVE UNIVERSITY





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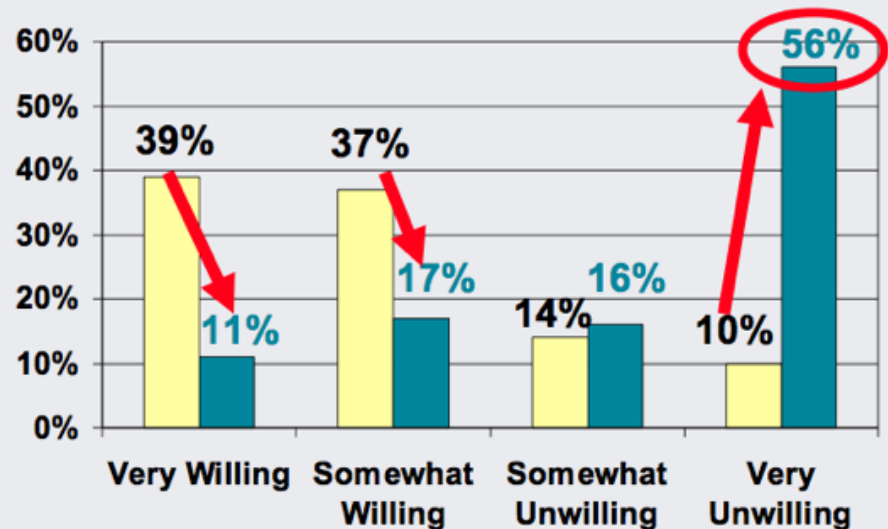
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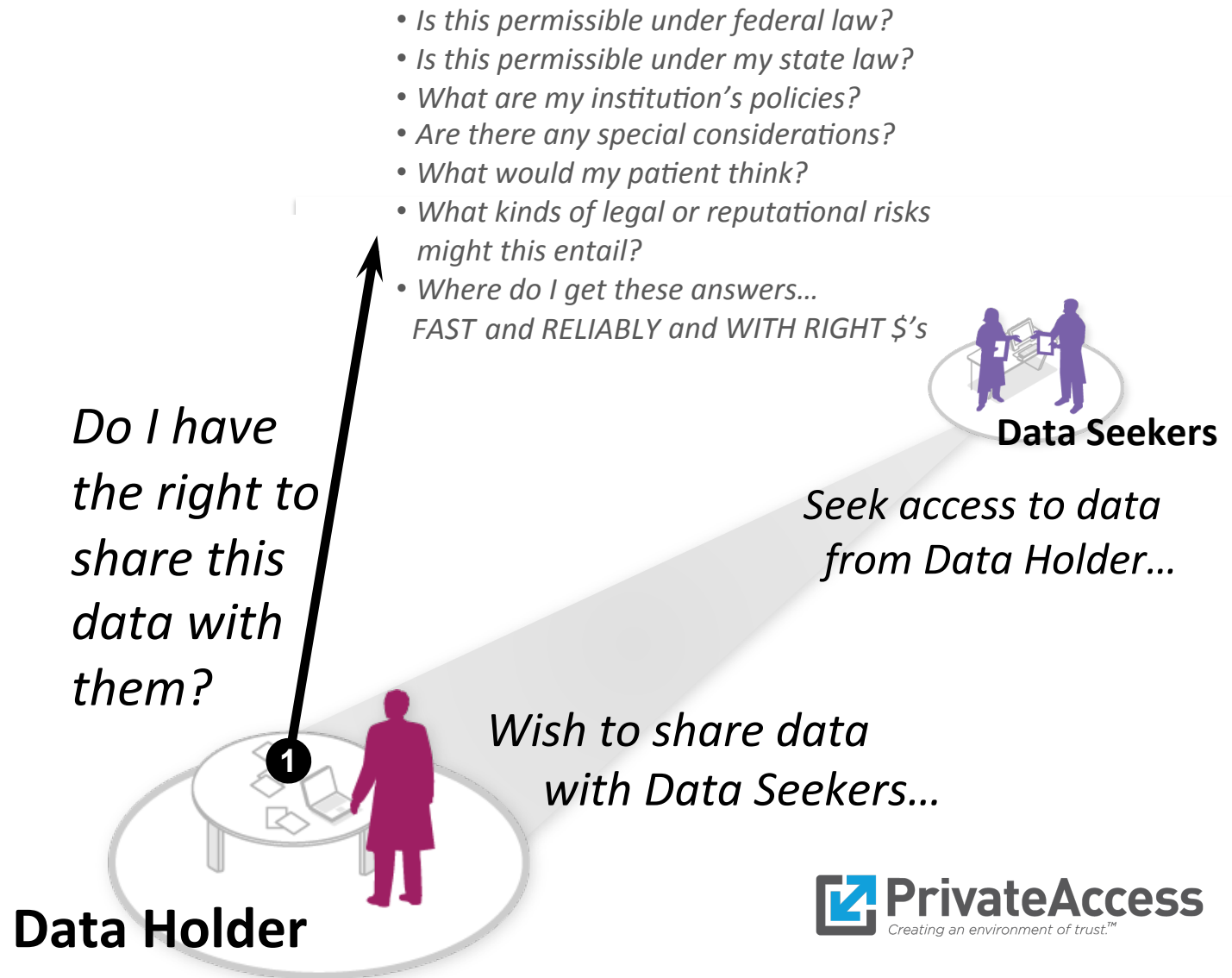
Multiple Other Studies Corroborate These Results

Remember when using an ATM was a mysterious and improbable experience

- 75% of Americans think their health care provider should use electronic health records, but 60% say they are not confident they will remain confidential (**42% say that potential risks outweigh benefit**)
- More than 700 cancer therapies clog the research pipeline partially because under 5% of patients enter clinical trials
- 30% of people decline to participate due to “concern their personal information would not be kept private and confidential”
- 57% of people would permit their PHI to be used for research only if various privacy-oriented conditions are met (**38% requiring notice and express case-by-case consent**)



A “Switch” (Not a “Store”) for Sharing Sensitive Data

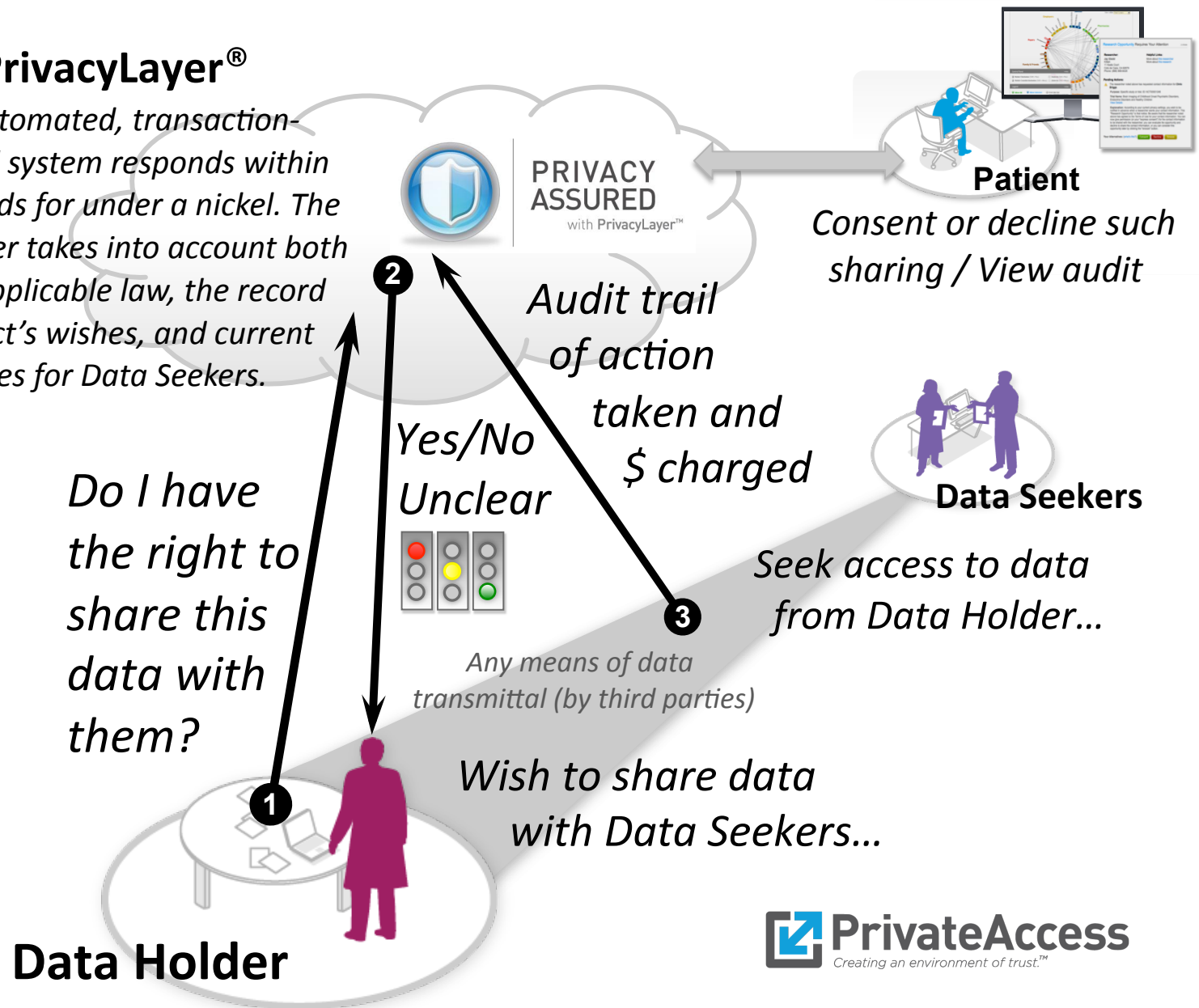




A “Switch” (Not a “Store”) for Sharing Sensitive Data

PrivacyLayer®

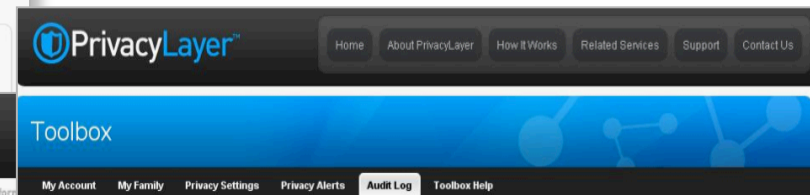
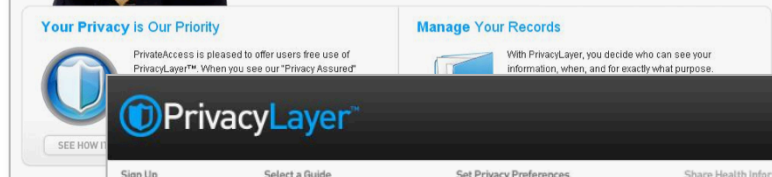
An automated, transaction-based system responds within seconds for under a nickel. The answer takes into account both the applicable law, the record subject's wishes, and current charges for Data Seekers.





Solutions So Far Directed to Registries and Biobanks

Technology that allows each person to grant “private access” to all or selected parts of their confidential personal information based on their particular needs and interests



Audit Log

Date/Time	Activity	Brief Explanation
7/9/2009 12:08:48 AM	Directive Created	Directive was created by Robert Chaitin for Robert Chaitin to enable all Researchers with access for contact
7/9/2009 12:08:47 AM	Directive Created	Directive was created by R search
7/9/2009 12:08:47 AM	Directive Created	Directive was created by R access for contact
7/9/2009 12:08:47 AM	Directive Created	Directive was created by R search
7/9/2009 12:08:47 AM	Directive Created	Directive was created by R contact
7/9/2009 12:08:47 AM	Directive Created	Directive was created by R
7/9/2009 12:01:27 AM	Login	Authentication confirmed for

Independent Identity Verification

Privacy Directives Language

Dynamic Consent Management

Comprehensive Audit Tracking

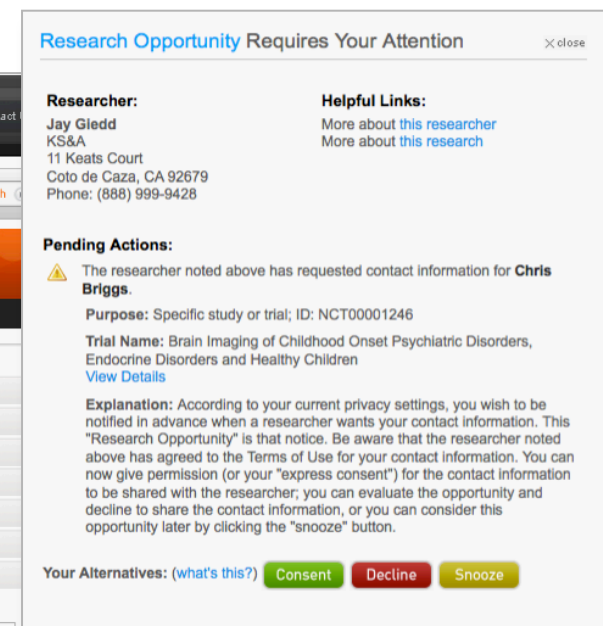
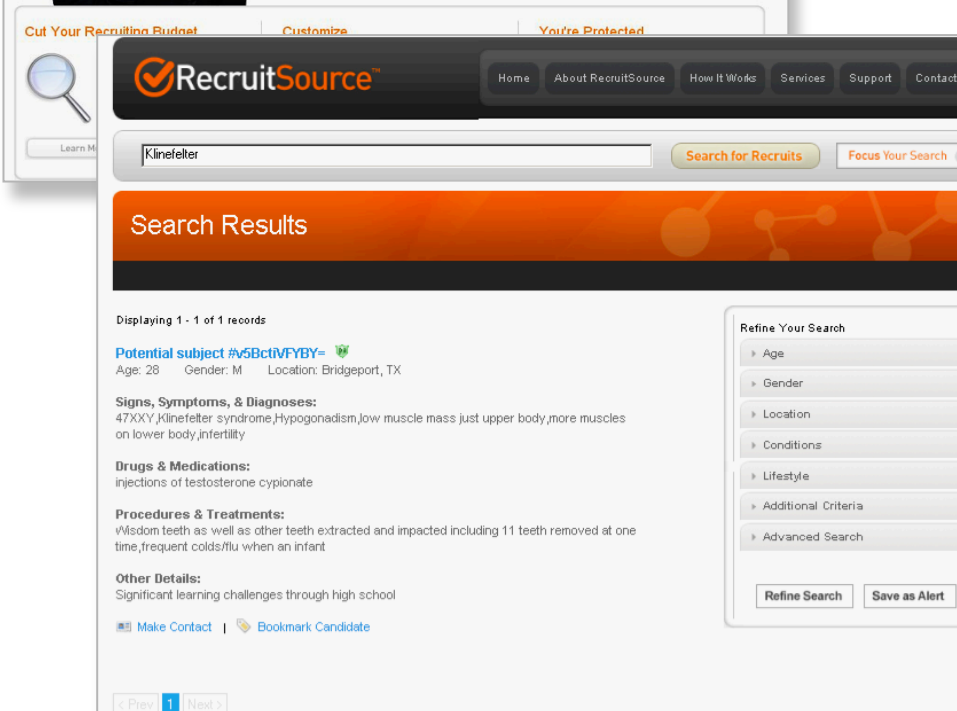
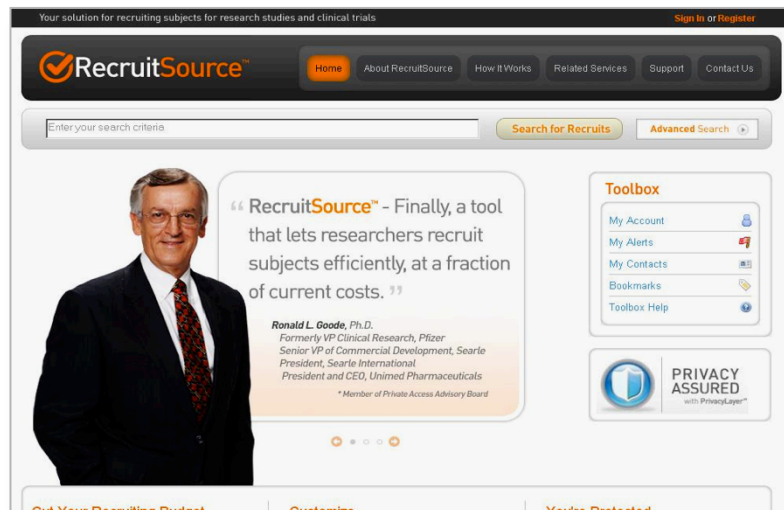
Integrated eCommerce Features





Initial Applications Focusing on Clinical Research

These private access grants can then be used by other services, such as recruitment for clinical trials, where the patients' consent empowers better data faster.





Results of Early Commercial Projects



- 1,200 patients and 5 researchers initially targeted
- 90% of patient users completing survey indicate positive experience – easy to use
- 75% would recommend to friends and family
- Partnering with a “trusted source” overwhelmingly drives patient participation



Current Research Underway

Informed Consent and Data Access in State-based Biobanks NIH Challenge Grant (October 1, 2009 – September 11, 2011)

ABSTRACT: To facilitate the development of state-sponsored population birth cohort databases for a wide range of studies, including genetics, research is urgently needed to address how recruitment, informed consent, and data access issues are affected by community members' hopes, expectations, and anxieties about research use of newborn blood spots.



- University of Michigan – Life Sciences and Society Program
- Private Access
- Johns Hopkins University
- University of Michigan – Community Based Public Health
- Michigan Biotrust for Health



Strong Support from Key Industry Stakeholders

“Patients are the most important stakeholders in medical research. By merging respect for their privacy with access to relevant and actionable medical information, we are giving patients more control over their destinies. This collaboration has the potential to accelerate medical progress by putting patients' needs front and center.”



Gregory Simon, Pfizer
Senior VP Worldwide Policy





Collaborations Focusing on Privacy as an Enabler



**Empowering Advocacy Groups
and Commercial Biobank**



**Clinical Trials
Information Platform**



**Informed Consent for
State-Based Biobanks**



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